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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,230	09/27/2001	Gil H. Choi	PB481US	3043

7590 08/25/2003

Human Genome Sciences Inc  
9410 Key West Avenue  
Rockville, MD 20850

[REDACTED] EXAMINER

TUNG, JOYCE

ART UNIT	PAPER NUMBER
1637	10

DATE MAILED: 08/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No. <b>09/830,230</b>  Examiner <b>Joyce Tung</b>	Applicant(s) <b>Choi et al.</b>  Art Unit <b>1637</b>	
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*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1)  Responsive to communication(s) filed on \_\_\_\_\_
- 2a)  This action is FINAL.      2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- 4)  Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) \_\_\_\_\_ is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claims 1-21 are subject to restriction and/or election requirement.

### Application Papers

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a)  The translation of the foreign language provisional application has been received.

- 15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                              | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | 6) <input type="checkbox"/> Other: _____                                    |

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## DETAILED ACTION

### *Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-8, 14 and 18, drawn to a first product which is an isolated nucleic acid molecule and the method of using the nucleic acid to detect *Borrelia* nucleic acids in a biological sample via hybridization, classified in class 536/435, subclass 23.1/6.

Group II, claim(s) 9, 11-12 and 20 drawn to a second product which is an isolated polypeptide and the kit containing the polypeptide, classified in class 530, subclass 350.

Group III, claim(s) 10 and 13, drawn to a third product which is an isolated antibody and antigens, classified in class 530, subclass 388.1.

Group IV, claim(s) 15, drawn to a forth product which is hybridoma, classified in class 435, subclass 346.

Group V, claim(s) 16, drawn to a fifth product which is a vaccine, classified in class 514, subclass 2.

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Group VI, claim(s) 17, drawn to a second method which is a method of preventing or attenuating an infection caused by *Borrelia* genus in an animal, classified in class 424, subclass 9.1.

Group VII, claim(s) 19, drawn to a third method which is to detect *Borrelia* nucleic acid via polymerase chain reaction, classified in class 435, subclass 91.2.

Group VIII, claim(s) 21, drawn to a forth method which is to detect *Borrelia* antibodies via an antibody-antigen complexes, classified in class 435, subclass 7.1.

2. The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The first group given is under PCT practice. And Groups II-VIII are based upon the US practice as discussed as follows:

Among Groups II-V, they are drawn to different products, for example, Group II is drawn to an isolated polypeptide, Group III is drawn to an isolated antibody and antigens, Group IV is drawn to a hybridoma and Group V is drawn to a vaccine. These products have different chemical structures and different usages, for example protein and antibody have very different chemical structure although they are protein, the protein can be used in for enzymatic function, the antibody can be used in immunoassay. Groups VI-VIII are drawn to different methods in which Group VI is drawn to a method of preventing or attenuating an infection caused by *Borrelia* genus in an animal, Group VII is drawn to a method to detect *Borrelia* nucleic acid via

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polymerase chain reaction, Group VIII is drawn to a method to detect *Borrelia* antibodies via an antibody-antigen complexes. These methods can be carried out with different materials, for example, Southern blot or immunoassay. Thus, they lack the same or corresponding special technical features.

3. These claims are generic to a plurality of disclosed patentably distinct restriction groups comprising different SEQ ID NOs. Applicant is required to elect no more than 1 disclosed nucleic acids or amino acid sequences even though this requirement is traversed.

Should applicant traverse on the ground that some or all of the different nucleic acids are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the nucleic acids to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. A telephone call was made to Mr. Lin Hymel on 8/18/2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently

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named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

***Sequence Rules***

6. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth as follows:

All the nucleic acid or amino acid sequences are required to have identification number, for example, in claim 1 and in table 1.

**APPLICANT IS GIVEN THE RESPONSE PERIOD SET FORTH IN THIS LETTER WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 CFR 1.821-1.825.** Failure to comply with these requirements will result in **ABANDONMENT** of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

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7. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

8. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

August 19, 2003



ETHAN WHISENANT  
PRIMARY EXAMINER